K071909

Barkey GmbH & Co. KG
Gewerbestrasse 8
D-33818 Leopoldshoehe
Germany

2.2 510(k) summary

OCT 18 2007

Date:	2007-10-06
Submitter:	Barkey GmbH & Co. KG
Address:	Gewerbestrasse 8 D-33818 Leopoldshoehe Germany
Contact:	Thomas Barkey
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Common Product Name:	Blood Warming Device
Trade Name:	**Prismacomfort blood warmer**
Regulation Medical Specialty (Panel):	Gastroenterology-Urology Devices [21 CFR 876.5820]
Product Code:	KOC
Device Class:	2
Identification of legally marketed predicate device to which substantial equivalence is claimed:	Stihler prismaflo 510(k) Number: K020103 Stihler Electronic GmbH Julius-Hoelder-Strasse 36 D-70597 Stuttgart-Germany [21 CFR 876.5820]

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Brief Description:

The Prismacomfort blood warmer is substantially equivalent in safety andeffectiveness to the legally marketed (predicate)Stihler prismaflo (510(k) Number: K020103).
The Prismacomfort blood warmer is used to warm the return blood flow line in order to replace heat lost to the athmosphere and effluent flow during a Prismaflex® treatment.
The Prismacomfort blood warmer consists of one controller and one sleeve warmer.
The controller (Barkey autocontrol 3XPT) controls the sleeve warmer (Barkey autoline XPT 4R) and displays alarm and status messages.
The Prismacomfort blood warmer warms the returning blood flow line by means of a silicon tube heat exchanger (applied part Barkey autoline XPT 4R) which covers the blood return flow line of the Gambro Prismaflex® system completely. The heat is transferred by the contact of the resistance heating system Barkey autoline XPT 4R to the inserted blood return line. The complete enclosure of the returning blood flow line to be warmed ensures that there are no temperature losses to the surroundings. The warmth produced by the sleeve warmer is therefore transferred to the return blood flow at maximum efficiency.
The device is intended for the Prismaflex® System and may be used with any of the Prismaflex® system therapy choices, when heat loss may cause undesirable cooling of the patient.

Intended Use:

The Prismacomfort blood warmer is used to warm the return blood flow line in order to replace heat loss to the atmosphere and effluent flow during a Prismaflex® treatment.

Federal law restricts this device to sale by or on the order of a physian.

It is intended to be used only by approriately trained and qualified healthcare professionals and servicing staff in clinical environments .

Summary of the technological characteristics of the Prismacomfort blood warmer:

The warmer is powerd with 24 VDC which is derived from 115 VAC (or where required 230 VAC), 50/60 Hz power supply and is controlled by an on-off switch on the front panel of the control unit Barkey autocontrol 3XPT. Below the on-off switch is a display temperature monitor.
The temperature of the sleeve warmer, visual and audible alarms, and other performance characteristics of the sleeve warmer are controlled electronically. Like the blood warmer Stihler prismaflo (510(k) Number: K020103; Stihler Electronic GmbH, Julius-Hoelder-Strasse 36, D-70597 Stuttgart-Germany), the sleeve warmer Barkey autoline XPT 4R is constructed as a slotted enclosed silicon tube which can completely enclose inserted blood return flow lines of up to 6.55 mm diameter.
The Prismacomfort weighs approx. 3.7kg and is equipped with a holder at the rear side of the control unit which allows mounting on hemodialysis system Gambro Prismaflex® system. Both products, the Prismacomfort and the Stihler prismaflo use sleeve warmers made of silicon. The flexibility of this material ensures a complete enclosure of the blood return flow line on Gambro Prismaflex® System.

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Summary of Nonclinical Tests and Results:

The Prismacomfort blood warmer complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested through validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- DIN EN 60601-1
- DIN EN 60601-1-2
- UL 2601-1/10.97
- CAN/CSA-C22.2 No. 601.1-M90
- ASTM F 2172-02

In order to verify performance of the Barkey Prismacomfort blood warmer in support of substantial equivalence, the following tests were carried out:

- Verify the ability of the system to prevent cooling down of blood return lines on Gambro Prismaflex CRRT system.
- Verify the ability of the system to protect the patient and to detect and alarm at unsafe operating conditions.

This shows that there are no new questions of safety and effectiveness for the Prismacomfort blood warmer as compared to the predicate device.

The predicate device (Stihler prismaflo (510(k) Number: K020103; Stihler Electronic GmbH, Julius-Hoelder-Strasse 36, D-70597 Stuttgart-Germany) has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order.

Conclusion:

The Prismacomfort blood warmer is substantially equivalent to the Stihler prismaflo (510(k) Number: K020103; Stihler Electronic GmbH, Julius-Hoelder-Strasse 36, D-70597 Stuttgart-Germany, [21 CFR 876.5820]) which received 510(k) approval on April 24, 2002. Both systems have the same intended use, and are capable of heating blood return flow line on Gambro Prismaflex®system. Both systems as intended according to the specifications of the device.
The Prismacomfort blood warmer is substantially equivalent in safety and effectiveness to the legally marketed (predicate) Prismaflo(510(k) Number: K020103).

The Prismacomfort blood warmer has the following similarities to the Prismaflo predicate device:

- have same intended use
- have same fundamental scientific technology and use the same operating priciple
- heating sleeves are constructed of identical materials
- both, the Prismacomfort and the Prismaflo give efficient heat to keep the blood return flow on Gambro Prismaflex® Systems warm.

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The main differences between the Prismacomfort blood warmer and the predicate Prismaflo are the structure. Due to the fact that the Barkey Prismacomfort is consisting of one controller and one applied part (the sleeve warmer), the Prismflo is one complete system which means that the warming device is fix connected to the supply part (the controller).

The predicate device (Stihler prismaflo (510(k) Number: K020103; Stihler Electronic GmbH, Julius-Hoelder-Strasse 36, D-70597 Stuttgart-Germany) has not been removed from the market at the initiative of the Commissioner of Food and Drugs or has not been determined to be misbranded or adulterated by a judicial order

In summary the Prismacomfort, described in this conclusion is substantially equivalent to the predicate device Stihler Prismaflo (K020103).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Mr. Thomas Barkey
Managing Director and Safety Officer
Barkey GmbH &t Co. KG
Gewerbestrasse 8
D-33818 Leopoldshoehe
GERMANY

Re: K071909
Trade/Device Name: Prismacomfort blood warmer
Regulation Number: 21 CFR §876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: KOC
Dated: October 6, 2007
Received: October 10, 2007

Dear Mr. Barkey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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2.1 Indications for Use

Indications for Use

510(k) Number (if known): K071909

Device Name: Prismacomfort blood warmer

Indications for Use: The Prismacomfort blood warmer is used to warm the return blood flow line in order to replace heat loss to the atmosphere and effluent flow during a Prismaflex® treatment.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071909